MAR 1 2 2012

PIONEER SURGICAL

510(k) Summary
Pioneer Posterior Cervico-Thoracic System

ADMINISTRATIVE INFORMATION

Contact:	Pioneer Surgical Technology 375 River Park Circle Marquette, MI 49855 Telephone: +1(906) 225-5602 Fax: +1(906) 226-4459 Emily M. Downs emilydowns@pioneersurgical.com
Date Prepared:	February 10, 2012

DEVICE NAME AND CLASSIFICATION

Trade/Proprietary Name:	Streamline Cervico-Thoracic (CT) System
Common Name:	Posterior Cervico-Thoracic System
Classification Regulations:	Spinal interlaminal fixation orthosis 21 CFR 888.3050, Class II Pedicle Screw Spinal System, 21 CFR 888.3070(b)(1), Class II
Product Code:	KWP, MNI, MNH
Classification Panel:	Orthopaedic and Rehabilitation Devices
Reviewing Branch:	Orthopedic Spine Devices Branch

INTENDED USE

The Pioneer Posterior Cervico-Thoracic System is indicated to promote fusion of the cervico- thoracic regions of the spine (C1-T3). The intended indications are as follows:

- Degenerative Disc Disease (as defined by neck or back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies)
- Spondylolisthesis
- Spinal Stenosis
- Fracture/ Dislocation
- Deformities or Curvature
- Tumors
- Pseudoarthrosis
- Revision of previous cervical and upper thoracic spine surgery

The use of the screws is limited to placement in the upper thoracic spine (T1-T3) in treating thoracic conditions only. The screws are not intended for use in the cervical spine.

The hooks and rods are also intended to provide stabilization to promote fusion following reduction of fracture/ dislocation or trauma in the cervical/ upper thoracic (C1-T3) spine.

K112757

DEVICE DESCRIPTION

The Pioneer Posterior Cervico-Thoracic System consists of a variety of rods, hooks, polyaxial screws, high-angle screws, locking caps, and connecting components used to build a cervico-thoracic spinal construct.

The Pioneer Posterior Cervico-Thoracic System components are manufactured from medical grade titanium alloy and medical grade cobalt chromium. Medical grade titanium alloy and medical grade cobalt chromium may be used together.

The Pioneer Posterior Cervico-Thoracic System can be attached to FDA approved pedicle screw systems (e.g. Quantum® Spinal Fixation System or Streamline TL Spinal System) using parallel connectors.

The system also contains Class 1 manual surgical instruments and cases that are considered exempt from premarket notification.

PREDICATE DEVICES

Posterior Cervico-Thoracic System (K092295), Pioneer Surgical Technology, Inc.

COMPARISON TO MARKETED DEVICE

Equivalency of this device is based on similarities in intended use, materials and design to other currently marketed posterior cervico-thoracic systems. Mechanical testing demonstrated comparable mechanical properties to the predicate device.

PERFORMANCE TESTING

Testing per recognized ASTM standards was presented (ASTM F 1717 Static and Fatigue, Compression and Torsional testing, ASTM F543 Screw Insertion and Screw Pullout testing).

CONCLUSION

Based on information presented in this submission, we conclude that the Pioneer Posterior Cervico-Thoracic System is substantially equivalent to predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Pioneer Surgical Technology, Incorporated
% Ms. Emily M. Downs
Manager, Regulatory Affairs
375 River Park Circle
Marquette, Michigan 49855

MAR 1 2 2012

Re: K112757
Trade/Device Name: Pioneer Posterior Cervico-Thoracic System
Regulation Number: 21 CFR 888.3050
Regulation Name: Spinal interlaminal fixation orthosis
Regulatory Class: Class II
Product Code: KWP, MNI, MNH
Dated: February 10, 2012
Received: February 13, 2012

Dear Ms. Downs:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K112757

Device Name: Pioneer Posterior Cervico-Thoracic System

Indications for use:
The Pioneer Posterior Cervico-Thoracic System is indicated to promote fusion of the cervico- thoracic regions of the spine (C1-T3). The intended indications are as follows:

- Degenerative Disc Disease (as defined by neck or back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies)
- Spondylolisthesis
- Spinal Stenosis
- Fracture/ Dislocation
- Deformities or Curvature
- Tumors
- Pseudoarthrosis
- Revision of previous cervical and upper thoracic spine surgery

The use of the screws is limited to placement in the upper thoracic spine (T1-T3) in treating thoracic conditions only. The screws are not intended for use in the cervical spine.

The hooks and rods are also intended to provide stabilization to promote fusion following reduction of fracture/ dislocation or trauma in the cervical/ upper thoracic (C1-T3) spine.

Prescription Use √ OR Over-the-Counter Use

(Per 21 CFR 801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K112757